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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/121,239 07/23/98 HARVEY

R GP091-02.UT

021365 HM12/0228  
GEN PROBE INCORPORATED  
10210 GENETIC CENTER DRIVE  
SAN DIEGO CA 92121

EXAMINER

SCHMIDT, M

ART UNIT

PAPER NUMBER

1635  
DATE MAILED:

02/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/121,239	HARVEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mary Schmidt *	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |  |  |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) ____.   |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 20) <input type="checkbox"/> Other:  |

Art Unit: 1635

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/00 has been entered.
2. Claims 1-20 are pending. The 35 U.S.C. 102 rejection of claims 19-20 is withdrawn in view of the following new rejection under 35 U.S.C. 103 of claims 19-20 and revised rejection of claims 1-18:

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunders et al. in view of Barany et al.

Saunders et al. is relied upon as set forth in the previous Official Action mailed 08/18/99.

In view of the amendments to claims 19-20, specifying the use of a non-ionic detergent, Barany et

Art Unit: 1635

al. is relied upon to teach use of 0.45% each of non-ionic detergents NP40 and Tween 20 for nucleic acid extractions (see col. 42, lines 20-44).

It would have been *prima facie* obvious for one of ordinary skill in the art to substitute the non-ionic detergent taught by Barany et al. for ionic detergent taught by Saunders et al. since Barany et al. exemplify use of the non-ionic detergents in the art for extraction of nucleic acids from cells.

One of ordinary skill in the art would have been motivated to use non-ionic detergents in methods of extracting nucleic acids from cells as taught by Barany et al. and thus would have been motivated to substitute such detergents in methods of nucleic acid extraction taught by Saunders et al.

One of ordinary skill in the art would have had an expectation of success to substitute the non-ionic detergents taught by Barany et al. for the ionic detergent taught by Saunders et al. since both types of detergents, ionic and non-ionic, are well-known in the art for extraction of nucleic acids from cells *in vitro*.

5. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eskola et al, Kacian et al., Saunders et al. in view of Rowley et al., Morris et al., vo Lindern et al., Goddard et al., Ohki et al. and Barany et al.

Barany et al. is newly added to the previous rejections made in the Official Action mailed 08/18/99. They are relied upon to teach use of 0.45% each of non-ionic detergents NP40 and

Art Unit: 1635

Tween 20 for nucleic acid extractions (see col. 42, lines 20-44). The therefore exemplify the use in the art of such non-ionic detergents.

For the same reasons argued above for the combination of Saunders et al. and Barany et al., it would have been *prima facie* obvious for one of ordinary skill in the art to substitute the non-ionic detergents taught by Barany et al. for the ionic detergent taught by Saunders et al. since both types of detergent are well-known in the art for extraction of nucleic acids from cells *in vitro*.

Applicant's arguments filed 12/15/00 have been fully considered but they are not persuasive.

Applicant argues that Eskola et al. does not anticipate the claimed invention for the reasons argued previously since the claims were amended to specify that the "probe hybridizes to either the first probe binding site or the second probe binding site" and Eskola et al. teaches a system where two probes are used to detect the hybridized sequences. In response, in view of the open "comprising" language, the instant claims still read on the invention of Eskola et al. since the open claim language allows for the addition of a second probe to detect the hybridized complexes.

Applicant's argument that Kacien et al. "Would not motivate one skilled in the art at the time the invention was made to make claimed invention, which uses a number of well defined steps reliant on specified structural elements... Nor would the disclosure of Kacian et al., which discloses isothermal amplification of nucleic acid, even if combined with other cited art, have

Art Unit: 1635

revealed a reasonable expectation of success in making the claimed present invention to one skilled in the art at the time Applicants' invention was made." As was argued previously, Kacien et al. teach methods for amplification of nucleic acids having genetic abnormalities via an amplification method which reads on the elements of the claimed invention in view of the open claim language.

The remaining references were cited to teach the known genetic abnormalities in the art which one skilled in the art would have been motivated to detect for the reasons argued previously. It was argued previously that one of ordinary skill in the art would have had motivation to apply the combination of the above references with these references for detection of known chromosomal alterations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, Katrina Turner, whose telephone number is (703) 305-3413.

M. M. Schmidt  
February 26, 2001

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER